UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

CALVARY HOSPITAL, INC.,

Plaintiff,

-v-

XAVIER BECERRA, in his official capacity as Secretary, United States Department of Health and Human Services,

Defendant.

OPINION AND ORDER

23-CV-8479 (GHW) (HJR)

HENRY J. RICARDO, United States Magistrate Judge.

Plaintiff Calvary Hospital, Inc. ("Calvary") is a provider of healthcare services. Corrected Complaint ("Compl.") ¶¶ 1–3, ECF No. 11. Like many such providers, Calvary is enrolled in the Medicare program, which is administered by Centers for Medicare & Medicaid Services ("CMS"), an agency of the United States Department of Health and Human Services ("HHS"). Compl. ¶¶ 4–6. Calvary filed this action to seek judicial review of a final decision by HHS pursuant to 42 U.S.C. § 1395ff(b)(1)(A), which provides that such proceedings are governed by 42 U.S.C. § 405(g).[1] Compl. ¶¶ 11–14. Defendant Xavier Becerra (the "Secretary") is sued in his official capacity as Secretary of HHS. Compl. ¶ 5.

[1] 42 U.S.C. § 405(g) refers to actions by the Commissioner of Social Security and the Social Security Administration, but 42 U.S.C. § 1395ff(b)(1)(A) explains that in Medicare appeals these references in Section 405(g) shall be considered references to the "Secretary" or the "Department of Health and Human Services," respectively.

Presently before the Court is Calvary's motion to compel completion of the administrative record of the HHS decision under review. ECF No. 36. Calvary claims that the administrative record improperly omits eight documents described in its motion papers. In opposition, the Secretary asserts that the administrative record is complete and should not include these eight documents because they were not considered by or tendered to the Administrative Law Judge ("ALJ") whose decision is under review. For the reasons described below, Calvary's motion is **DENIED**.

I. FACTUAL BACKGROUND

The facts set forth below are drawn from the Corrected Complaint (ECF No. 11) or from the briefs submitted on this motion.[2] With limited exception, the background facts pertinent to this motion are not disputed.

A. Medicare Provider Appeals

The Medicare program pays providers, such as Calvary, that deliver healthcare services to eligible Medicare beneficiaries. *See* Compl. ¶ 50. The Secretary has delegated to CMS authority to determine whether Medicare covers particular medical services. *See Townsend v. Cochran*, 528 F. Supp. 3d 209, 211 (S.D.N.Y. 2021) (providing overview of Medicare coverage and agency appeal process). CMS contracts with third-party Medicare Administrative Contractors

[2] Calvary's memorandum of law in support of its motion, ECF No. 37, is cited as "Calvary Br." The Secretary's opposing memorandum of law, ECF No. 44, is cited as "Secretary Br." Calvary's reply memorandum of law, ECF No. 45, is cited as "Calvary Reply."

("MACs") to administer certain day-to-day functions of the Medicare program. *Id.*; Compl. ¶¶ 47, 65, 67.

Because it is not feasible to confirm in advance whether Medicare actually covers services to be provided, Medicare operates on an "honor system" whereby CMS pays providers' vendors first, subject to the right to audit these payments later. Secretary Br. at 2. A payment that CMS determines it should not have made is described as an overpayment. *Id.* at 3.

These post-payment audits are conducted by CMS contractors known as Unified Program Integrity Contractors ("UPICs"). Compl. ¶ 57. A UPIC typically reviews a random sample of the provider's Medicare claims over a certain period and calculates an error rate (*i.e.*, the percentage of claims that were improperly paid) based on that review. *See* 42 U.S.C. § 1395ddd(f)(8). If the error rate is sufficiently sustained or high, the UPIC extrapolates that error rate across the provider's other Medicare claims to determine the size of the overpayment. *See* 42 U.S.C. § 1395ddd(f)(3). If the provider disputes the UPIC's overpayment determination, it can follow the four-step administrative appeal process described below. *See Townsend*, 528 F. Supp. 3d at 212–13 (describing four-step process from the perspective of a beneficiary, as opposed to a provider).

(1) Redetermination. The provider can seek redetermination by the MAC. Compl. ¶¶ 118–19; 42 U.S.C. § 1395ff(a)(3).

(2) Reconsideration by QIC. The provider can then seek reconsideration by a different contractor, a Qualified Independent Contractor ("QIC"), which can consider additional evidence. *See* Compl. ¶¶ 120–22; 42 U.S.C. § 1395ff(c).

(3) Administrative Law Judge Hearing. A provider dissatisfied with reconsideration by the QIC can request a hearing by an Administrative Law Judge. Compl. ¶¶ 123–25; 42 U.S.C. § 1395ff(d)(1). The ALJ issues a decision based on evidence presented at the hearing or otherwise admitted into the administrative record. 42 C.F.R. § 405.1046(a)(1).

(4) Medicare Appeals Council. A provider can appeal from the ALJ's decision to the Medicare Appeals Council of HHS. *See* Compl. ¶¶ 126–27; 42 U.S.C. § 1395ff(d)(2)(A). The Council has 90 days to issue a decision, which becomes the final decision of the Secretary. 42 U.S.C. § 1395ff(d)(2)(A). If the Council does not issue a decision within this 90-day period, the provider can file suit to obtain judicial review, in which case the ALJ decision becomes the Secretary's final decision. 42 U.S.C. § 1395ff(d)(3)(B); 42 U.S.C. § 1395ff(b)(1)(A); Compl. ¶¶ 128–130. Such proceedings are governed by 42 U.S.C. § 405(g).

B. Calvary's Administrative Process

While it is not necessary to this motion to describe the full details of Calvary's administrative proceedings in this matter, the key milestones are summarized below.

In November 2019, a UPIC, SafeGuard Services, LLC ("SafeGuard"), sent Calvary a letter finding that there was an approximately $3.7 million overpayment on Medicare claims based on an extrapolation from a review of a sample of claims.

See Compl. ¶ 200. The UPIC revised this amount to approximately $4.1 million in March 2020. Compl. ¶ 201. The UPIC explained that the claims reviewed in the sample were selected from a "universe" of claims from a certain period and having certain features, including that more than zero was paid on such claims. *See* Compl. ¶¶ 203–05. In other words, the UPIC excluded so-called "zero-pay" claims from the "universe" from which it selected the sample. From that universe, the UPIC created a "sampling frame" from which it randomly selected a group of claims described as a statistically valid random sample (a "SVRS"). Compl. ¶¶ 206–07. The UPIC estimated the total overpayment to Calvary based upon an analysis of the individual claims within the SVRS.

Calvary requested a redetermination in May 2020, and the MAC (National Government Services, Inc. or "NGS") upheld the UPIC determination. Compl. ¶¶ 212-15. Calvary then submitted a Request for Reconsideration to the QIC in December 2020. In April 2021, the QIC (C2C Solutions, Inc. or "C2C") found that the UPIC defined a valid sample, but overruled the UPIC's determinations as to certain individual claims within the sample. Compl. ¶¶ 223–24. In May 2021, the UPIC issued a letter with a revised extrapolation, finding an overpayment of approximately $2.7 million. Compl. ¶ 225.

Calvary then requested an ALJ hearing to appeal from the QIC decision. Compl. ¶ 227. Among other things, Calvary argued to the ALJ that the UPIC's sampling and extrapolation methodology was invalid because it improperly excluded "zero-pay" claims from the "universe" used to create the sampling frame

and the SVRS. Compl. ¶ 240. The ALJ rejected this argument, finding that "the Universe is not required to contain all paid and unpaid claims or all claims submitted by the appellant during the selected time period." Compl. Ex. 1; ECF 11-1 at page 10 of 43 (original numbering in ALJ decision).

After this unfavorable ALJ decision, Calvary sought review by the Appeals Council, but then filed the instant action after the Appeals Council failed to issue a decision within 90 days. Compl. ¶¶ 247–48.

C. The Documents That Calvary Seeks to Add to the Administrative Record

Calvary seeks to add eight documents to the administrative record and they are described below as Items One through Eight for clarity of reference.[3] As descried in more detail below, none of these eight Items was submitted to the ALJ.

1. One PI Shared Systems Report

The terminology used in the parties' briefing to describe Item One is confusing, so some discussion of Item One is in order. As described above, the UPIC (SafeGuard) assembled a "universe" of claims from which it created a "sampling frame" from which it drew a SVRS. One of Calvary's central complaints in this action is that the SVRS did not include zero-paid claims.

Confusingly, the parties use the word "universe" to describe two different collections of Medicare claims. For clarity, the undersigned uses the term

[3] Calvary's brief lists seven items (*see* Calvary Br. at 1 and 9), but the item listed second (all documents regarding SafeGuard's recalculation) appears to be two different SafeGuard worksheets (*see* Calvary Br. at 21–22), which are described as Items Two and Three below.

"universe" to describe the collection of claims from which the UPIC created the sampling frame. This "universe" did not include any zero-paid claims.

Item One is a report of a larger collection of claims (*i.e.*, larger than the "universe") that was contained in a document that the UPIC described as the "One PI Shared Systems Report." *See* Calvary Br. at 14. The UPIC stated that it obtained Item One from CMS. *Id.* Significantly for Calvary's argument on the merits, Item One *did* include zero-paid claims. *See id.* at 15–16. Calvary refers to this larger collection of claims constituting Item One as the "Target Universe," but it is different from the smaller "universe" described above. It is undisputed that the UPIC started with the claims included in Item One, but then filtered out, *inter alia*, zero-paid claims to create the collection that the UPIC calls the "universe." From there, having filtered out the zero-paid claims, the UPIC created the sampling frame and the SVRS. *See* Calvary Br. at 15-16.

Calvary contends that it needs Item One to assess the validity of the sampling and extrapolation process, while the Secretary argues otherwise. Although Item One included claims that Calvary had submitted, meaning that Calvary theoretically could have recreated it, it is undisputed that Calvary never obtained Item One, *i.e.*, the specific report that the UPIC says it obtained from CMS. Because Calvary did not have Item One, it is undisputed that Calvary never submitted Item One to the ALJ. Indeed, Calvary's argument on the merits is that HHS's decision should be overturned due to a failure to provide this information. *See* Compl. ¶ 259.

2. UPIC Worksheet demonstrating steps in "Calculating the Designated Overpayment in the Sample"

After the QIC issued a decision that was partially favorable to Calvary, the UPIC sent Calvary a May 2021 letter with a revised extrapolation, finding an overpayment of approximately $2.7 million. Compl. ¶¶ 224–25. While the UPIC's March 2020 letter explaining its sampling methodology included a worksheet demonstrating its steps in "Calculating the Designated Overpayment in the Sample," the UPIC's May 2021 letter did not include a similar worksheet. Calvary Br. at 19-22. Calvary claims that the UPIC created a similar worksheet for its May 2021 letter (*i.e.*, Item Two) and that Calvary needs this worksheet to recreate all steps taken by the UPIC in its recalculation process. It is undisputed that Calvary does not have Item Two, and that Item Two was not submitted to the ALJ.

3. UPIC Worksheet demonstrating steps in "Determining the Average Overpayment per Claim in Sample," "Estimating the Designated Overpayment in the Universe," and "Calculating the Interval Estimate"

Item Three is similar to Item Two. Indeed, Calvary's opening brief groups these two Items together as "all documents regarding [the UPIC's] recalculation of the overpayment amount following a partially favorable Reconsideration Decision." Calvary Br. at 1.

In short, Item Three is a worksheet that Calvary says was included in the UPIC's March 2020 letter, but that was omitted from the UPIC's May 2021 letter recalculating the extrapolated overpayment amount after the QIC's partially favorable April 2021 decision. Calvary Br. at 21–22. As is the case for Item Two,

Calvary says it needs this worksheet, but it is undisputed that Calvary does not have Item Three and that Item Three was not submitted to the ALJ.

4. The April 16, 2020 Demand Letter from NGS to Calvary

Page one of Calvary's opening brief identifies this letter by date and page nine describes it as the "Second Demand Letter." Calvary filed a copy of the "Second Demand Letter," dated April 16, 2020, as Exhibit 1 to the Declaration of Stephen D. Bittinger. ECF No. 38-1. In substance, this letter demanded payment of $4,084,249.26 from Calvary. Confusingly, page 24 of Calvary's brief refers to this letter as both the "First Demand Letter" and the "Second Demand Letter," but Calvary did not file the "First Demand Letter" with its motion, so the Court assumes that Calvary intended to refer to the "Second Demand Letter" and that Item Four is the April 16, 2020 letter from NGS filed at ECF No. 38-1.

Calvary claims the ALJ cited Item Four in his decision. Calvary Br. at 24. But the cited page from the administrative record does not mention this April 16, 2020 letter. *See* Calvary Br. at 24 (citing AR Vol. 1 p. 110). Page 110 of Volume 1 of the Administrative Record, which is page 2 of 43 of the ALJ decision, refers only to events in 2021 and later. The immediately preceding page of the record (Page 109 of Vol. 1 or page 1 of 43 of the ALJ decision) refers to the *underlying fact* communicated by Item Four (*i.e.*, "a change in the extrapolated overpayment amount to $4,084,249.26"), but does not refer to April 16, 2020 *letter itself*. Instead, the ALJ decision cites as support for the $4,084,249.26 demand Exhibit 1, D at p. 89 of the record before the ALJ. The Secretary says, without rebuttal, that this document is at page 3238 of Volume 1 of the Administrative Record. Secretary Br.

at 24. The Court has reviewed page 3238 of Volume 1 of the Administrative Record and confirms that it is an *April 20*, 2020 letter from NGS to Calvary advising that Calvary will receive a corrected demand letter for an overpayment amount of $4,084,249.26. It is not Item Four.

Accordingly, Calvary does not demonstrate that Item Four was cited in the ALJ decision or otherwise submitted to the ALJ. The April 20 Letter actually cited by the ALJ is already contained within the administrative record. Moreover, there does not appear to be any dispute regarding the fact that NGS issued a demand for an overpayment in the amount of $4,084,249.26 in or about April 2020.

5. The October 21, 2020 Letter from Calvary to the UPIC (SafeGuard) Requesting Additional Information

Like Item Four, Calvary claims the ALJ cited this letter in his decision. Calvary Br. at 24. But the cited page of the ALJ decision, AR Vol. 1, page 110, does not mention Item Five or the fact that Calvary requested additional information from SafeGuard. Calvary's brief also cites Page 236 of Volume 1 of the Administrative Record. This is the second page of a three-page letter, dated June 10, 2021, from Calvary's counsel to the ALJ. This page of the record refers to the letter from SafeGuard dated October 21, 2020 (*i.e.*, Item Five), but does not state that this letter is attached or otherwise demonstrate that Calvary sent Item 5 to the ALJ. Accordingly, Calvary has not demonstrated that Item Five was submitted to the ALJ.

6. The June 14, 2021 Partial Refund Letter from NGS to Calvary

While Calvary's opening brief refers to this letter (Calvary Br. at 6, 9), the portion of the brief said to address Item Six, Section III.D, provides no specific information about why this letter should be included in the administrative record. *See* Calvary Br. at 9 (referring to Section III.D for a discussion of the "Partial Refund Letter"). Page 110 of Volume 1 of the Administrative Record refers to the fact that, after the QIC's partially favorable decision, "the extrapolated overpayment amount was recalculated as $2,719,225.59." While this is the same fact communicated by Item Six (*see* ECF No. 38-4), the ALJ decision does not cite Item Six (dated June 14, 2021) for this point, but instead cites Exhibit 2 to the ALJ decision, which is described as a May 13, 2021 letter. Thus, Calvary makes no showing that the ALJ cited or otherwise considered Item Six.

7. The December 13, 2022 Hospice Provider Statistic and Reimbursement System Summary Report

Calvary describes Item Seven as a file that the UPIC (SafeGuard) used and that is referenced in an expert report that Calvary submitted to the ALJ. Calvary Br. at 24–5. But Calvary never claims it submitted Item Seven itself to the ALJ or that the ALJ considered Item Seven in making his decision. Given that Calvary's expert cited Item Seven, it appears that Item Seven was available to Calvary, but it was not submitted to the ALJ.

8. The Replication code.sas File Enclosed with a November 13, 2020 Response

Calvary says this file was produced by the UPIC (SafeGuard), which shows it was available to Calvary. Calvary Br. at 25. But Calvary never claims it attempted to submit Item Eight to the ALJ.

Summary

Calvary does not demonstrate that it submitted any of the eight documents in question to the ALJ. To the contrary, Calvary acknowledges that it does not have Items One, Two and Three, and makes no showing that they were otherwise provided to ALJ. Items Four, Five and Six are pieces of correspondence in Calvary's possession. Calvary makes no showing that it submitted any of these Items to the ALJ or that the ALJ decision otherwise cited them. Finally, Items Seven and Eight are documents that Calvary appears to have obtained from the UPIC, but Calvary fails to show were properly before the ALJ.

II. ANALYSIS

The eight documents that are the subject of this motion were not submitted to or considered by the ALJ, whose decision is under review in this action. Thus, this motion poses the question of whether a district court can add to the administrative record documents that were *not* submitted to or considered by the ALJ, but that allegedly were considered by HHS contractors, *i.e.*, the MAC and the UPIC. Importantly, this decision does not address Calvary's arguments on the merits as to what evidence the ALJ or any of the Medicare contractors *should have* obtained, produced, or reviewed. In particular, Calvary contends that the random

sampling process was flawed, *inter alia*, because the SVRS did not include zero-paid claims, and that Calvary did not receive documents needed to replicate the analysis conducted by the Medicare contractors.

A. Prior Decisions

Although this specific motion appears to be an issue of first impression in this District, four other courts have considered essentially the same question. As described below, three of these courts have denied motions to complete or to supplement the administrative record with materials not presented to the ALJ. One court has granted such a motion. The same attorney representing Calvary here represented the plaintiffs in all four of these cases.

The first of these decisions was *Compass Lab. Servs. v. Becerra*, No. 22-cv-2770, Dkt. No. 45 (W.D. Tenn. Jul. 24, 2023). That court denied the plaintiff's motion to "supplement" the record to include the full universe of claims, including zero-paid claims, used by a Medicare contractor in conducting its review. Citing *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71 (2d Cir. 2006), the court determined that 42 U.S.C. § 405(g) controlled what evidence the court could consider in its review of the ALJ decision, and that this Medicare statute displaced the Administrative Procedure Act (the "APA") on the question of whether the administrative record can be supplemented. Slip op. at 5. Next, the court concluded that judicial review under Section 405(g) is based on a "closed administrative record" such that "neither party may put any additional evidence before the district court." *Id.* at 7 (*citing Matthews v. Weber*, 423 U.S. 261, 271 (1976)). Accordingly, the court determined that the only option for considering

additional evidence provided by Section 405(g) is to remand the case back to the ALJ. Finally, the court distinguished other decisions allowing supplementation of the record under different circumstances. Slip op. at 8–9.

Approximately four months later, a Magistrate Judge in the Southern District of Florida denied two similar applications styled as motions to "complete" the administrative record. *MedEnvios Healthcare, Inc. v. Becerra*, 23-cv-20068, 2023 WL 9692087 (S.D. Fla. Nov. 27, 2023), *adopted by* 2024 WL 551837 (S.D. Fla. Feb. 12, 2024). That court viewed plaintiff's applications as disguised motions to "supplement" the record similar to the motion addressed in *Compass Lab Services*. The court denied plaintiff's motions because, "[a]t bottom, [plaintiff] seeks to obtain materials never reviewed by the ALJs." *Id.* at *13. The District Judge overruled plaintiff's objections to the Magistrate Judge's decision. 2024 WL 551837. In particular, after considering plaintiff's argument based on 42 C.F.R. § 405.1042(a)(2), the District Judge concluded that it does not undermine the conclusion "that documents that were never even part of the universe of evidence offered to the ALJ do not need to be included in the record for it to be complete." *Id.* at *4. The court also rejected the plaintiff's arguments that "a Medicare contractor is an agency decisionmaker for purposes of an appeal to a district court or that an administrative record must contain every document created by an agency and its contactors at any point during the course of the matters on appeal, regardless of whether they were part of the record on which the final agency decision was made." *Id.* at *4.

The third decision siding with HHS was *Ashlie Healthcare, Inc. v. Becerra*, 23-cv-1443, 2024 WL 3890104 (E.D. Cal. Aug. 21, 2024). That court denied plaintiff's motion to complete the administrative record after concluding that there was no evidence that either the ALJ or any of the Medicare contractors had considered the documents in question. *Id.* at *1. Further, the court noted that plaintiff's argument for including these materials in the record was inconsistent with its merits argument that the agency erred in failing to consider these same materials: "Plaintiff cannot now argue that a universe file including zero-paid claims was considered by the agency, when the theory it advances is premised on the fact that the agency *failed* to consider those claims." *Id.* at *2 (emphasis in original).

The one decision siding with the plaintiff was *Goose Creek Physical Med., LLC v. Becerra*, 22-cv-3932, 2024 WL 942918 (D.S.C. Mar. 5, 2024) (granting motion to compel completion of administrative record). That court concluded that documents that were considered by the agency were not included in the administrative record and that plaintiff had identified those documents specifically. *Id.* at *11. Further, the court found that plaintiff provided clear evidence that the Medicare contractors "acted on behalf of the agency" and relied on the documents at issue, "which are not currently included in the administrative record before the court." *Id.* at *11. Although the court did not specify whether it was relying on Section 405(g) or the APA, it cited authorities applying both statutes. Finally, in discussing Section 405(g), the court referred to review of "the MAC's final decision"

and "the MAC's factual findings," although the statute refers to the "Commissioner of Social Security," which is construed to mean the Secretary of HHS per 42 U.S.C. § 1395ff(b)(1)(A). *Id.* at *4. Thus, the court apparently viewed the Medicare contractors as equivalent to the Secretary.

B. 42 U.S.C. § 405(g) Is the Sole Avenue for Judicial Review

The first question on this motion is whether it must be determined under 42 U.S.C. § 405(g) or the Administrative Procedure Act (the APA), 5 U.S.C. § 551, *et seq*. The Secretary asserts that Section 405(g) entirely supplants the APA in the judicial review of Medicare decisions, and that this Medicare statute does not allow a district court to add to the administrative record. Secretary Br. at 9–13. The only way to consider additional evidence that was not before the ALJ, according to the Secretary, is to remand the case to HHS, assuming the requirements for doing so are met. *Id.* Calvary argues that because Section 405(g) does not address motions to complete the record, the APA controls, and the APA allows for completion of the administrative record under the circumstances presented here. Calvary Br. at 9–10.

Starting with the text of these statutes, the APA governs the process for obtaining judicial review of agency action except to the extent other "statutes preclude judicial review." 5 U.S.C. § 701(a)(1). The Medicare statute provides for "judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title," with any reference to the "Commissioner of Social Security" or the "Social Security Administration" in 405(g) being considered a reference to the "Secretary" or the "Department of Health and Human Services,"

respectively. 42 U.S.C. § 1395ff(b)(1)(A). Section 405(h) reads, "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency *except as herein provided*." 42 U.S.C. § 405(h) (emphasis added).

The Second Circuit discussed the interplay between Section 405(g) and the APA in *Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71 (2d Cir. 2006), which figures prominently in the briefing. Another court deciding a similar motion described this decision as "the only guidance to directly resolve this issue of dueling grants of judicial review in the Medicare context." *Compass Lab Svcs. v. Becerra*, Dkt. No. 45 at 5. Each side claims that *Yale-New Haven Hospital* supports its position. Calvary contends that *Yale-New Haven Hospital* stands for the proposition that the APA provides the standard for completion of the administrative record in an appeal from a final agency decision by HHS. Calvary Br. at 9. Accordingly, Calvary cites authorities applying the APA. *See* Calvary Br. at 10–14. The Secretary, however, claims that Calvary's starting premise is incorrect and that the content of the administrative record is determined exclusively by Section 405(g). Secretary Br. at 9–11.

The Secretary has the better of this argument. The *Yale-New Haven Hospital* decision arose from an action seeking judicial review of a decision by the HHS Appeals Council, which constituted the final agency decision in that case.[4] This agency decision, which found that certain payments made to the plaintiff were

[4] In contrast, there was no Appeals Council decision in the instant case, so the ALJ decision is the final agency action here.

improper, was grounded in a provision of a 1986 Medicare reimbursement manual prohibiting payment for medical devices that had not yet received FDA approval. The plaintiff hospital challenged the adverse HHS decision, *inter alia*, on the basis that HHS's promulgation of this 1986 manual provision was "arbitrary and capricious" under the APA, and thus could not properly provide the basis for the agency's decision. The Second Circuit concluded that the HHS Secretary had acted arbitrarily and capriciously in promulgating this manual provision within the meaning of 5 U.S.C. § 706(2)(A), and thus vacated the HHS decision for relying on "an invalid and unenforceable rule." 470 F.3d 71, 86.

Contrary to Calvary's suggestion, *Yale-New Haven Hospital* did not address a motion to complete the record or determine which statute governs such an application. Instead, the Second Circuit recognized that 42 U.S.C. § 405(g) is "the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." 470 F.3d at 78 (*quoting Heckler v. Ringer*, 466 U.S. 602, 615 (1984)). However, because a subsequent statute, such as the Medicare Act, can only supersede or modify the APA to the extent it does so expressly, the Second Circuit ruled, "where no provision of § 405(g) is on point, we apply the judicial review provisions of the APA." *Id.* Accordingly, the Second Circuit applied the judicial review provisions of the Administrative Procedure Act in determining the validity of the 1986 manual provision, which is not a subject addressed in Section 405(g). *Id.* (citing 5 U.S.C. § 559).

Based on *Yale-New Haven Hospital*, the question becomes whether Calvary's motion raises a question for which "no provision of § 405(g) is on point." If so, the APA would apply. Turning to the portion of Section 405(g) that is relevant here, it sets forth the standard for judicial review of a "final decision" of the Secretary. Such review must be based on the Secretary's filing of "a certified copy of the transcript of the record including the evidence upon which the findings and decisions complained of are based." 42 U.S.C. § 405(g). These findings are conclusive if supported by substantial evidence. *Id.* This statute also describes the circumstances in which additional evidence can be considered:

> The court may, on motion of the [Secretary] made for good cause shown before the [Secretary] files the [Secretary's] answer, remand the case to the [Secretary] for further action by the [Secretary], and it may at any time order additional evidence to be taken before the [Secretary], but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the [Secretary] shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the [Secretary's] findings of fact or the [Secretary's] decision, or both, and shall file with the court any such additional and modified findings of fact and decision . . . .

Id. Thus, Section 405(g) both (a) specifies what constitutes the administrative record, and (b) provides a mechanism to add to that record. Calvary, however, argues that Section 405(g) is silent as to how to complete the administrative record, which means that the APA controls. But the instant motion is different in kind from the question presented in *Yale-New Haven Hospital*. In that case, the basis for plaintiff's challenge HHS's decision was a defect in a prior

rulemaking process: the promulgation of a manual provision. That separate rulemaking process was unquestionably governed by the APA, which explains why the Second Circuit applied the APA in its analysis.[5] Calvary's motion is very different – it challenges the agency's determination of what constitutes the administrative record. Section 405(g) expressly addresses the contents of the administrative record and the circumstances under which it can be expanded. Accordingly, *Yale-New Haven Hospital* does not require application of the APA to these questions.

An earlier district court decision in the *Yale-New Haven Hospital* case further supports this conclusion. In addition to addressing the validity of the 1986 manual provision, the Second Circuit affirmed the district court's earlier decision to strike certain declarations that the Secretary had offered to supplement the record. *Yale-New Haven Hosp.*, 470 F.3d at 81. This holding is pertinent to the facts presented here, and the district court's decision granting the motion to strike is instructive. The district court explained that in actions seeking judicial review of HHS decisions, "the scope of this Court's review is limited to the pleadings and transcripts from the administrative proceedings, including all evidence considered by the Administrative Law Judge ('ALJ')." *Yale-New Haven Hosp., Inc. v. Thompson*, 198 F. Supp. 2d 183, 185 (D. Conn. 2002), *aff'd*, 470 F.3d 71. Because

[5] *See also Art of Healing Medicine, P.C. v. Burwell*, 91 F. Supp. 3d 400, 418-19 (E.D.N.Y. 2015) (describing *Yale-New Haven Hospitals* as "finding that because section 405(g) does not provide for judicial review of administratively adopted rules, the court of appeals analyzed the rule relied upon by the Department of Health and Human Services under the judicial review standards of the APA").

the declarations in question were never submitted to the ALJ or to the Appeals Council, the court found they were not part of the administrative record and could not be considered. That court explained, "[t]he only evidence not presented to the ALJ or Appeals Council below, which this Court may consider, is 'material evidence' that for 'good cause' shown was not presented at the administrative level." *Id.* at 185 (citing 42 U.S.C. § 405(g)). Thus, the district court was of the view that Section 405(g) provided the exclusive means to consider evidence not presented to the ALJ or to the Appeals Council. *See also Townsend v. Cochran*, 528 F. Supp. 3d 209, 215 (S.D.N.Y. 2021) (rejecting argument that APA applies and finding "the APA standard does not apply in Medicare appeals pursuant to 42 U.S.C. § 1395ff, and thus does not apply in this case"); *Fratellone v. Sebelius*, 08-cv-3100 (RMB) (RLE), 2009 WL 2971751 at *9 (S.D.N.Y. 2009) (in a Medicare appeal under Section 405(g), "[t]he ALJ's determination creates the entire and complete record of the case").

Additionally, of the four courts that have addressed motions similar to Calvary's, the only court directly deciding whether Section 405(g) provides the exclusive means for expanding the administrative record concluded that it does. *Compass Lab. Servs. v. Becerra*, slip op. at 7–8. That court found that the language of Section 405(g) "is thus applicable to the issue of what evidence the Court may consider in its review of the ALJ's determination, displacing the APA on the issue of supplementing the record." *Id.* at 5.[6]

[6] The other three decisions addressing similar motions did not squarely decide this issue. In *MedEnvious*, the Magistrate Judge's decision, which was adopted, acknowledged there were differing views as to whether Section 405(g) or the APA controlled, but concluded it did not matter because the controlling Eleventh Circuit applied the same standard under

Calvary's motion does not seek remand to HHS and its opening brief presents no argument that it meets the standard set by Section 405(g) for "additional evidence to be taken" before the Secretary. Only on reply does Calvary claim that this standard it met. *See* Calvary Reply at 10. It is improper to make an argument for the first time on reply. But even considering Calvary's new argument under Section 405(g), the proper remedy would be a remand to the agency, not a review of the existing agency decision on an expanded record, which is the relief that Calvary seeks through the instant motion.

C. Alternatively, Calvary Fails to Satisfy the APA Standard

Even assuming that that APA applies, Calvary's motion would be denied under that statute as well. Thus, Calvary would not prevail even if it were correct about the APA applying to this motion. *See MedEnvios v. Becerra*, 2023 WL 9692087 at *6 (finding the issue of whether to add material to the record is the same under both the APA and Section 405(g)).

To start, the parties have opposing positions on which APA decisions are most relevant to this motion. Calvary cites decision from a "broader APA context" to argue that the administrative record includes "more than merely what was before a final agency decision maker." Calvary Br. at 11 (citing cases at 12-14). In response, the Secretary argues that because Calvary seeks judicial review of a

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both statutes. *Id.* at *6. Similarly, *Ashli* found, "[t]he court need not decide whether the Social Security Act or the Administrative Procedure Act provides the standard of review applicable to this motion." 2024 WL 3890104 at *1. The court in *Goose Creek* cited cases applying both statutes without explaining its apparent conclusion that Section 405(g) did not supplant the APA.

formal agency adjudication, the appropriate APA analog is the standard provided by 5 U.S.C. § 556(e), which is that "[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision." Secretary Br. at 13. These materials become the record for judicial review under the APA. *See* 5 U.S.C. § 706(2)(E). According to the Secretary, the materials that are the subject of this motion would not be part of the administrative record under 5 U.S.C. § 556(e) because they were never before the ALJ. Secretary Br. at 14.

On reply, Calvary notes that the Secretary "fails to cite a single case that references 5 U.S.C. § 556 in the context of Medicare reimbursement appeals." Calvary Reply at 8. But the absence of such decisions is consistent with the Secretary's position that only Section 405(g), not the APA, applies to Medicare appeals. While Calvary argues that Medicare appeals would not fall within 5 U.S.C. § 556 because they need not be "on the record" adjudications, this argument is inconsistent with Paragraph 91 of Calvary's Complaint, which cites Medicare regulations to describe the agency process as follows: "The ALJ's decision 'must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions.' [42 C.F.R.] § 405.1046(a)(1). Further, the ALJ's decision may not be based on extra-record documents. *Id.*" Compl. ¶ 91. It is also inconsistent with the Supreme Court's observation that judicial review under 42 U.S.C. § 405 is based on a "closed administrative record."

Matthews v. Weber, 423 U.S. 262, 270 (1976) (observing that, under Section 405(g), "neither party may put any additional evidence before the district court.").

As the Secretary points out, the decisions that Calvary cites in support of its argument that the record extends beyond what was presented to the ALJ are disanalogous because they arose from less formal agency proceedings.[7] Indeed, one of these same decisions explained why there is room for debate as to what constitutes the administrative record for an *informal* agency adjudication:

> The Court's statutory obligation is to evaluate Secretary Ross's decision in light of the "whole record," 5 U.S.C. § 706, which must include all materials that were "before [him] . . . at the time he made his decision," *Overton Park,* 401 U.S. at 420, 91 S.Ct. 814. But this is not a case in which, because of the nature of the administrative proceedings below (such as agency adjudication or notice-and-comment rulemaking), either Secretary Ross or the Department of Commerce compiled an "administrative record" in the course of *making* his decision. Instead, as is often the case with "informal" agency actions, Secretary Ross amassed some information, consulted it, and made his decision on that basis. Then, only *after* these lawsuits were filed, the Department of Commerce conducted a search for materials that were "before" the Secretary at the time he made that decision, compiled those materials, and submitted them to the Court as the "Administrative Record."

[7] *See, e.g.*, *Center for Biological Diversity v. U.S. Fish & Wildlife Svc.*, 21-cv-5706-LJL, 2022 WL 2805464 (S.D.N.Y. Jul. 18, 2022) (judicial review of finding that a particular species was not threatened or endangered); *Comprehensive Cmty. Dev. Corp. v. Sebelius*, 890 F. Supp. 2d 305 (S.D.N.Y. 2012) (denying motion to expand the administrative record in action challenging grant funding decision); *Saget v. Trump*, 375 F. Supp. 3d 280 (E.D.N.Y. 2019) (challenge to termination of Haiti's Temporary Protected Status determination); *U.S. Court Security Officers v. U.S. Marshall Svc.*, 22-cv-1380, 2023 WL 2758354 (S.D.N.Y. Apr. 3, 2023) (challenge to alleged decision to exclude plaintiffs from CARES Act distribution where defendant claimed that no administrative record existed).

New York v. Dep't of Commerce, 351 F. Supp. 3d 502, 631 (S.D.N.Y. 2019), *aff'd in part, reversed in part sub nom. Dep't of Commerce v. New York*, 588 U.S. 752 (2019). Here, in contrast, a record was compiled in the course of the ALJ making his decision. Assuming that the APA applies, the decision at issue here would be reviewed under 5 U.S.C. § 556(e), and the materials that Calvary wishes to include would not fall within what this statute defines as "the exclusive record for decision."

But even under the standard applied for judicial review of informal agency adjudications, Calvary falls short of demonstrating that "completion" of the administrative record is appropriate here. Where the agency assembles the record for judicial review under the APA, "deference is due to the agency's judgment as to what constitutes the whole administrative record." *Comprehensive Community Dev. Corp. v. Sebelius*, 890 F. Supp. 2d, 305, 309 (S.D.N.Y. 2012). Where a party seeks to show that materials exist that were actually considered but are not in the record as filed, that party must show that the materials sought to be added "were before the agency *decision-maker*." *Id.* (emphasis in original). "It is not enough to show that these materials were somewhere within the agency because 'interpreting the word 'before' so broadly as to encompass any potentially relevant document existing within the agency . . . would render judicial review meaningless. *Id.* (citation omitted) (*quoting Fund for Animals v. Williams*, 245 F. Supp. 2d 49, 57 n.7 (D.D.C. 2003)).

Although the eight documents that Calvary seeks to add to the record were not before the ALJ, Calvary contends they were considered by HHS contractors, the

MAC and the UPIC, during the administrative process, and that these contractors qualify as agency decision-makers for purposes of completing the record. Calvary Reply at 7–8. In considering this argument, the starting point is 42 U.S.C. § 1395ff(b)(1)(A), which provides for "judicial review of the Secretary's final decision after such hearing as is provided in section 405(g)."[8] Because this Court can only review "the Secretary's final decision," the question becomes who qualifies as "the Secretary" for these purposes. On this point, the Secretary argues that he can delegate this power to a "member, officer, or employee" of HHS under 42 U.S.C. § 405(l). This provision does not refer to the Medicare contractors. Calvary, on the other hand, contends that the ALJ "is not the sole agency decision-maker" in the Medicare context, citing regulations that treat the QIC as an agency-decisionmaker. *See* Calvary Br. at 12 (citing 42 C.F.R. §§ 405.1046(a)(3), 405.1106(b), 405.1132 and 405.990). As discussed below, these regulations do not support Calvary's conclusion.

First, Calvary argues that 42 C.F.R. § 405.1046(a)(3) provides that an ALJ determination of the amount of payment due is "not binding on the contractor for purposes of determining the amount of the payment due." However, the next sentence of this regulation explains that the payment amount determined by the

[8] This provision is subject to part (2), which allows for expedited access to judicial review in certain circumstances. As discussed below, Calvary cites regulations pertaining to this process in support of its position. However, this action is not the product of expedited access to judicial review under Section 1395ff(b)(2). It is instead an action for judicial review under Section 1395ff(b)(1). *See* ECF No. 11 ¶¶ 12–14 (alleging this action seeks judicial review of "a final agency decision of the Secretary" and citing Section 1395ff(b)(1)(A)).

contractor in effectuating an ALJ decision "is a new initial determination under § 405.924," meaning that it is then subject to redetermination and the other administrative appeal steps. 42 C.F.R. § 405.1046(a)(3). Because a contractor's payment determination is subject to these further steps, it does not constitute final agency action.

Calvary also cites 42 C.F.R. § 405.1106(b), which allows an appeal to bypass the ALJ or the Appeal Council, but only if the ALJ and Council fail to act within applicable deadlines. 42 C.F.R. § 405.1132 is a general provision that allows escalation to federal court if the Appeals Council fails to make a timely decision. 42 C.F.R. § 405.990 allows for expedited judicial review "in place of an ALJ hearing or Council review," but use of this process requires that there be "no material issue of fact in dispute" and that a "review entity" certifies that the Council does not have authority to decide the relevant question of law or regulation. Significantly, this "review entity" includes three reviewers who are ALJs or members of the Departmental Appeal Board. C.F.R. § 405.990. Thus, access to this expedited judicial review process is controlled by HHS employees, not contractors.

Even assuming that Calvary correctly characterizes these regulations as providing circumstances where "a QIC's decision could be the final agency decision" (Calvary Br. 12), Calvary does not contend that this case arises from any of those contexts (*e.g.*, where there is no decision by the ALJ or the Appeal Council) and Calvary cites no statute or regulation treating the QIC as the Secretary here. The only decision Calvary cites to support its claim that Medicare contractors count as

agency decision-makers in this context is the *Goose Creek* decision. While Calvary is correct that *Goose Creek* treated Medicare contractors as agency decision-makers, *Goose Creek* did not ground this conclusion in any statute or regulation. In the absence of an analysis explaining how the Medicare contractors can be treated as the Secretary in *this context*, and in light of Calvary's argument that there are *other contexts* where regulations *do* treat Medicare contractors as the final agency decision-maker, the undersigned respectfully declines to follow *Goose Creek* on this point. Finally, even assuming that "a QIC's decision could be the final agency decision," Calvary contends that most of the Items it seeks to add to the administrative record (specifically, Items One, Two, Three, Seven and Eight) were considered by the UPIC, not the QIC.

D. 42 C.F.R. § 405.1042(a)(2) Does Not Support Calvary

Calvary also cites 42 C.F.R. § 405.1042(a)(2), which describes the content of the administrative record for certain Medicare hearings:

> The record will include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

Calvary seizes upon the reference to evidence "not considered by the ALJ," claiming that it applies to the evidence that was not produced to Calvary. Calvary Reply at

5. But the context of this language suggests that it means evidence that was submitted or proffered to the ALJ unsuccessfully. This was how the Ninth Circuit apparently interpreted Section 405.1042(a)(2) in *Goffney v. Becerra*, 995 F.3d 737, 747 (9th Cir. 2021) (referring to "any proffered evidence excluded by the adjudicator"). Indeed, it would make little sense to include within the administrative record evidence that was never submitted to the ALJ. Drawing an analogy to litigation practice, the record in the Court of Appeals does not contain documents that were not produced in discovery. The failure to require production might be an issue raised on appeal, but the record is limited to what was actually presented to the trial court. Accordingly, Section 405.1042(a)(2)'s reference to "any evidence excluded or not considered" must mean evidence offered during the hearing, but that the ALJ decided not to admit. *See* 42 C.F.R. § 405.1028 (describing ALJs' authority to admit or exclude evidence from consideration).

Calvary makes a second argument based on Section 405.1042(a)(2) – that because this regulation refers to all three of "the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision," "the appealed determinations" must be something different from "the ALJ's . . . decision," and must therefore refer to determinations by the Medicare contractors, which means that any documents that the contractors used in making their determinations are part of the administrative record. Calvary Reply at 4. This argument is unavailing. Construing Section 405.1042(a)(2) as requiring the ALJ to obtain and include in the administrative

record every single document that any Medicare contractor used is both unrealistic and inconsistent with other regulations governing ALJ hearings. 42 C.F.R. § 405.1034 authorizes the ALJ to request information from the QIC, but only if the ALJ "believes that the written record is missing information that is *essential to resolving the issues on appeal* and that information can be provided only by CMS or its contractors" (emphasis added). Additionally, Section 405.1037 provides for discovery in ALJ hearings "only when CMS or its contractor elects to be a party to an ALJ hearing." 42 C.F.R. § 405.1037(a)(1). Even where discovery is available, it applies to "a matter that is relevant to the specific subject matter of the ALJ hearing." *Id.* § 405.1037(a)(2). In light of these provisions, which signal that the ALJ cannot and should not obtain every document in the possession of the QIC or other CMS contractors, the reference in Section 405.1042(a)(2) to "documents and other evidence used in making the appealed determinations" cannot be construed to mean that the administrative record must contain every single document in the possession of the Medicare contractors, whether submitted to the ALJ or not. Such a construction would place an unrealistic burden on the ALJ, who has limited power to compel production of such materials, and who has a limited time in which to assemble the administrative record and render a decision. *See* 42 C.F.R. § 405.1016(a) (requiring ALJ to issue a decision "no later than the end of the 90 calendar day period beginning on the date the request for hearing is received").

E. Calvary Fails to Satisfy the Standard for Supplementation of the Record

In short, Calvary's motion is a request for the Court to consider materials that are not properly part of the agency's administrative record. Calvary acknowledges that such requests are evaluated "rigorously." Calvary Br. at 13; *see Nat'l Audubon Soc. v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997) (extra-record evidence can only be considered "when there has been a strong showing in support of a claim of bad faith or improper behavior on the part of the agency decisionmakers or where the absence of formal administrative findings makes such investigation necessary in order to determine the reasons for the agency's choice").

Calvary's opening brief does not address this standard. On reply, Calvary's primary argument is that the Secretary misconstrues this motion as seeking to supplement the record rather than to complete it. Calvary Reply at 9. While Calvary's Reply argues, in the alternative, that supplementation is appropriate, it cites *Fratellone v. Sebelius* as authority for the proposition that a reviewing court can consider an affidavit that was not in the administrative record. Calvary Reply at 10. But in that case, the court considered the affidavit in question because it did not "introduce new and material evidence." *Fratellone*, 2009 WL 2971751 at *7. Instead, the court viewed the affidavit an aid to understanding the evidence that was part of the record. *Id.* In contrast, Calvary claims the documents in question in the present action "are essential to Plaintiff's claims challenging the validity of the statistical sampling and extrapolated overpayment." Calvary Reply at 10. Accordingly, Calvary's motion is a far cry from the facts of *Fratellone*.

Finally, while Calvary alleges that the Secretary and his contractors "willfully, deliberately and unjustifiably" withheld information from Calvary, Compl. ¶ 260, it does not and cannot contend that the agency decision-maker, *i.e.*, the ALJ, compiled the administrative record in bad faith. To the contrary, the ALJ acknowledged and addressed Calvary's primary argument, concluding, "the Universe is not required to contain all paid and unpaid claims or all claims submitted by the appellant during the selected time period." ECF No. 11-1 at page 10 of 43. Disagreeing with Calvary over which claims were relevant is not improper behavior by the agency. While Calvary is free to challenge these findings on the merits, it cannot expand the administrative record to include materials not submitted to the ALJ.

III. CONCLUSION

For the reasons described above, Calvary's motion is **DENIED**. The Clerk of Court is respectfully directed to close the motion at Docket Number 36.

SO ORDERED

Dated: January 15, 2025
New York, New York

Hon. Henry J. Ricardo
United States Magistrate Judge